REMARKS/ARGUMENTS

This is in response to the official action of January 11, 2008. Claims 1 and 24 have been amended to clarify that the distal protection device is secured to the hypotube. Claim 1 also has been amended to reflect that the distal protection device is expandable and contractable about the hypotube. Applicants have submitted with this response the Declaration under 37 C.F.R. §1.132 of Bruce Flight to demonstrate that the examiner's conclusion that a syringe may be considered as a hypotube is unreasonable.

CLAIM REJECTIONS – 35 U.S.C. §112

Reconsideration is requested of the rejection of all pending claims under 35 U.S.C. §112, first paragraph as failing to satisfy (a) the written description requirement and (b) the enablement requirement. Both of these theories are based on a conclusion that a previous amendment said "...to define further that the hypotube has an outer diameter dimension to enable the therapeutic catheter to be advanced onto and along the guidewire..." was not described in the specification to reasonably convey that the inventor had possession of the claimed invention at the time the application was filed and also that there was no description in the specification that was enabling of that limitation. The rejection plainly is incorrect for reasons discussed below.

The Written Description Requirement

The function of the description requirement is to ensure that the inventor had possession, as of the filing date of the application relied on, of the specific subject matter later claimed by him. *In re Smith*, 481 F.2d 910, 178 USPQ 620 (CCPA 1973). It is not necessary that the application describe the claim limitations exactly, but only so clearly that persons of ordinary skill in the art will recognize from the disclosure that the applicants in fact invented what was ultimately claimed. *In re Lukach*, 442 F.2d 967, 169 USPQ 75 (CCPA 1971), *In re Smythe*, 480 F.2d 1376, 178 USPQ 279 (CCPA 1973).

In determining whether the written description requirement has been satisfied, the primary consideration is factual and depends on the nature of the invention and the amount of

knowledge imparted to those skilled in the art by the disclosure. *In Re Smythe*, supra. The level of ordinary skill must be taken into account.

The "written description" also includes the drawings, and, in some cases, the drawings alone may be sufficient to satisfy the "written description" of the invention. *Vas-Cath, Inc. v. Mahurkar*, 93 F.2d 1555, 1563, 19 U.S.P.Q.2d 1111, 1116 (Fed. Cir. 1991). The facts and the drawings, however, must disclose the claimed inventions efficiently so that one of ordinary skill would recognize that it was part of the original invention. It is legally insignificant whether the disclosure is found in the specification or in the drawings so long as it is there. *In Re Wolfensperger*, 302 F.2d 950, 133 USPQ 537 (CCPA 1962). "...it must be shown that a person of ordinary skill would have understood at the time the patent application was filed that the description requires that limitation." "The written description must include all of the limitations of the [claim], or [it must be shown] that any absent text is necessarily comprehended in the description provided and would have been so understood at the time the patent application was filed." *Hyatt v. Boone*, 47 USPQ 1128 (Fed. Cir. 1998).

Here, the only element in the claims asserted in the rejection not to have been in applicants' possession is the limitation that the hypotube has an outer diameter to enable the therapeutic catheter to be advanced onto and along the guidewire. That assertion is wholly unsupported by evidence and apparently ignores the elementary fact, that would be known by one skilled in the art that the inherent purpose of a guidewire is to provide a guiding function for a catheter. It also is elementary that that function is achieved by threading the catheter onto the guidewire so that the catheter can follow along the guidewire to an intended vascular destination. To assert that applicants were not in possession of that aspect of the claimed invention is to ignore completely applicants' written description. Applicants' paragraph 0027 explains that the hypotube may serve as a guidewire to permit a catheter to be advanced through torturous [sic] vasculature to distal arterial locations. Paragraph 0027 also incorporates by reference the teaching of U.S. patent 6,068,623 which explains: "The thin wire over which the catheter rides is commonly referred to as a 'guidewire,' obviously, because it guides the therapy balloon to the treatment location." (1:38-40). See also the reference at paragraph 0034 of the application that "An aspiration catheter then may be inserted into the blood vessel over or alongside the guidewire..." Indeed, even one having the most rudimentary, elementary knowledge of catheters

and guidewires would recognize that in order for a catheter to be advanced onto and along a guidewire, the guidewire necessarily must be dimensioned with respect to the guidewire lumen in the catheter to enable the catheter and guidewire to perform their well-known cooperative function. There is no basis for the assertion that the applicants were not in possession of a hypotube guidewire with an outer dimension that would enable a catheter to be used as intended with a guidewire. In any guidewire-catheter combination it is inherent that the outer diameter of the guidewire be such as to enable a catheter to be advanced onto and along the guidewire. A person of ordinary skill would have recognized that applicants were in possession of the dimensional relationship between a guidewire and a catheter. See the Declaration of Bruce Flight submitted herewith.

Enablement

Similarly, there is no basis for the assertion that there is no enablement for the limitation that the hypotube outer diameter enables the catheter to be advanced onto and along the guidewire. As discussed above, that is an essential element for any guidewire-catheter combination. Even one of minimal skill in the art would recognize and be able to make and use a catheter and guidewire that, in order to be operative , would require the hypotube to have an appropriate outer dimension. The hypotube necessarily has that characteristic. See also, the Declaration under 37 C.F.R. §1.132 of Bruce Flight, submitted herewith. The rejection provides no supportive reasoning and should be withdrawn.

CLAIM REJECTIONS – 35 U.S.C. §102

Reconsideration is requested of the rejection of each of the claims as anticipated under 35 U.S.C. §102(b) by Kimmell patent 3,952,747. Kimmell is directed to a device for deploying a filter in a blood vessel by delivering the filter to the region where it is to be deployed and then ejecting the filter to release it into the blood vessel. Upon deployment, the filter is no longer disposed on the delivery device and cannot be contracted or recaptured by the delivery device. The device and the filter are illustrated in FIGS. 1, 4 and 5, reproduced below.

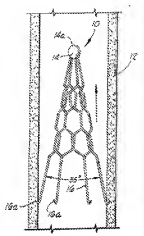

FIG. 1

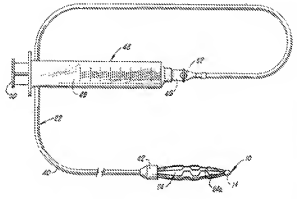

FIG. 4

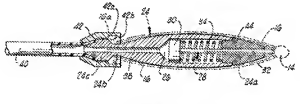

FIG. 5

The filter is placed in the vena cava to prevent blood clots from migrating into the pulmonary circulation. (1:11-25). Once the filter has been ejected from the delivery device, its legs spring outwardly to assume a generally conical configuration and hooks at the ends of the legs bite into and impale the walls of the blood vessel to secure the filter in place (FIG. 1). (3:53-61).

The device includes an ejector assembly 28 (FIG. 5) that holds the filter in a low profile, delivery configuration in readiness to be released and deployed in the vena cava. The ejector assembly is operated hydraulically by a syringe 48. As is apparent from Kimmell, the syringe 48 "...is of conventional construction ..." (6:56-59). The hydraulic system is actuated by first connecting the outlet fitting of the syringe with a fitting 46 at the proximal end of the catheter and then depressing the plunger 50. No part of the plunger, of course, enters into the lumen of the catheter 40 or the fitting 46. The plunger 50 remains entirely within the barrel of the syringe. That is conventional syringe construction. The catheter and syringe are separate, distinct elements.

Applicants' invention relates to a guidewire for guiding a catheter to an intravascular location. A distal protection device is secured to the distal end of the guidewire. As explained in the written description, the distal protection device may be deployed, temporarily during the operation of the catheter, to prevent emboli from being carried downstream from the treatment site. To further clarify the nature of the invention, claim 1 had been amended to require that the hypotube is dimensioned to enable a therapeutic catheter to be advanced onto and along the guidewire. Claim 1 also requires the hypotube guidewire to include slave and master actuating members with the master actuating member having a portion disposed within the proximal portion of the lumen of the hypotube.

To the extent that the rejection relies on Kimmell as disclosing a hypotube, that is incorrect. Kimmell makes no mention of hypotubing. It merely refers to the catheter 40. Additionally, to the extent that the rejection is based on the notion that the syringe 48 is part of a "hypotube", that is an unreasonable and arbitrary interpretation. As explained in the Flight Declaration, hypotubes are well known in the art and have a commonly understood meaning. A syringe and a catheter are separate elements with the syringe typically being substantially larger in diameter than the catheter with which it is used. As such elements are disclosed by Kimmell, neither is reasonably considered as being "hypotubing." Additionally, Kimmell does not disclose a guidewire, much less a guidewire in the form of a hypotube having an outer diameter dimensioned to enable a therapeutic catheter to be advanced onto and along the guidewire. To the extent that the rejection is based on the premise that the syringe is part of the catheter, that would be inconsistent with a guidewire function. Another catheter could not be advanced over

either or both the syringe and the catheter 40 and the rejection provides no evidence of a catheter being advanced over a syringe. The simple answer is the obvious, that Kimmell does not disclose a guidewire, does not disclose a hypotube and does not disclose a guidewire capable of enabling a therapeutic catheter to be advanced onto and along the device.

The fundamental error in the analysis in which the rejection is based is apparent from the statement in the rejection that "...Kimmell's tube 48 is considered as a hypotube due to given its broadest reasonable interpretation. (sic)" Such interpretation is plainly incorrect and unreasonable. The rejection points to no evidence that a syringe may reasonably be considered as a hypotube and there is no evidence of prior art disclosing the passage of a catheter over a syringe. There is no evidence that one skilled in the art would reasonably consider a syringe to be a hypotube or vice versa. To the contrary see the Flight Declaration.

In addition, claim 1 has been amended to recite that the distal protection device is secured to the guidewire so that it can be expanded and contracted about the guidewire. Kimmell fails to disclose this feature as well. In Kimmell, as discussed above, the vena cava filter is deployed by releasing it into the vena cava. Upon deployment it is separated from the delivery catheter. It is not secured as required by claim 1 so that it can be expanded and collapsed about the catheter 22 and certainly not about a guidewire or a hypotube guidewire, neither of which are disclosed in Kimmell.

Finally, an explanation is requested of the statement suggesting something had been mischaracterized by the applicants. Applicants thoroughly disagrees with that conclusion. Unfounded, unexplained allegations of mischaracterization by an applicant are inappropriate in an official action, particularly where there is nothing to substantiate it.

The rejection should be withdrawn.

Respectfully submitted,

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